

REMARKS

Claims 1-5, 8, 13-15, 17-54 are pending in the instant application. Claims 20-48 have been withdrawn from consideration pursuant to a restriction requirement. At the outset, Applicant gratefully acknowledges the indication of allowability of Claims 8 and 52-54. In the most recent Office Action, Claims 1, 3, 9, 11, 13, 14, 17-19, 49 and 50 were rejected under 35 USC § 102(e) as allegedly anticipated by U.S. Pat. No. 6,132,370 to Furnish, et al. (hereinafter, "Furnish"). Claims 4 and 5 were rejected under 35 USC § 102(e) as allegedly anticipated by U.S. Pat. No. 6,210,323 to Gilhuly, et al. (hereinafter, "Gilhuly"). Claims 2, 15 and 51 were rejected under 35 USC § 103(a) as allegedly obvious over Furnish. Claim 5 was also rejected under 35 USC § 112, second paragraph, for indefiniteness due to a lack of proper antecedent basis.

As amended above, Claim 5 has been corrected to cure the lack of antecedent basis. Applicant respectfully submits that the rejection for indefiniteness has been obviated. Favorable reconsideration and withdrawal of the rejection is kindly requested.

Claim 1, as amended above, recites an apparatus for stabilizing an epicardial surface of the heart comprising, *inter alia*, a foot having at least two arms, one arm being longer than the other, which length is defined between the proximal and distal ends and within a plane defined by the bottom surface of said foot. This feature is fully supported by the specification generally, and more specifically, is illustrated at, among other places, Figs. 36-38. No new matter has been added.

In contrast to the claimed invention, Furnish discloses a coronary stabilizer comprising simply two generally cylindrical prongs (32). In Fig. 6, and the accompanying description at

Col. 4, lines 4-12, Furnish describes that at least one of prongs (32) may have an additional section (42). However, only Fig. 6 shows the manner in which these additional sections are implemented. As shown, the additional sections extend in a direction that deviates sharply away from the plane defined by the bottom surface of the prongs. This is inconsistent with the teachings of the present invention, and contrary to the amended claims.

With respect to Claim 3, this claim should be patentable for at least the same reasons as Claim 1, from which it depends. Claim 3 is also separately patentable. Claim 3 recites, *inter alia*, the bottom surface having lateral surfaces which taper away from the plane of the contact surfaces. In contrast to Furnish, the only contact surfaces are on an underside of the cylindrical prongs (See Fig. 6, 46). There is no teaching or suggestion of a lateral surface, and no further teaching that any lateral surface tapers away from the contact surface. The omnibus reference to Cols. 5 and 6 in their entirety, and the omitted figure reference, are not helpful to illustrate or support the rejection.

With respect to Claim 13, as amended, this claim includes a contact surface that is generally convex when viewed along a central axis defined by the slot. The most stark contrast between Claim 13 and Furnish is seen in Figs. 1 and 4 of Furnish. Therein, Furnish shows an end view of its bifurcated member 30. It can clearly be seen that the prongs 32 are merely cylindrical, and do not form a generally convex contact surface. Moreover, the only teaching to deviate from the cylindrical prongs is illustrated in Fig. 6, where the contact surface 46 is generally planar, not convex. Further, regarding Claim 14, again Furnish does not offer any teaching or suggestion of a lateral surface, and no further teaching that any lateral surface tapers away from the contact surface.

Claim 49 also recites, *inter alia*, a lateral surface attached thereto, said lateral surface tapering away from said contact surface to be generally convex. As discussed above, this feature is lacking from Furnish. Claim 50 is separately patentable, but is submitted as patentable for at least the same reasons as Claim 49, from which it depends.

It has been decided by the courts that “Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim.” *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir., 1984). Therefore, Applicant respectfully submits that Claims 1, 3, 13, 14, 49 and 50 are patentably distinguished over Furnish, and kindly requests that the rejection be reconsidered and withdrawn.

Regarding Claim 17, the method recited includes placing a foot in engagement with the heart so that the coronary artery is positioned in the slot and the first arm retracting the apex of the heart. There is no teaching or suggestion in Furnish regarding the use of the stabilizer for retracting an apex of the heart, as recited in the claims. There is not so much as a mention of the apex of the heart anywhere in Furnish. Moreover, it would be doubtful that an artisan of ordinary skill would view the configuration of Furnish’s stabilizer as conducive to retraction of the apex.

To support a *prima facie* case of anticipation by inherency, the limitation in question must “necessarily” be present in the prior art reference. *In re Robertson*, 169 F.3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999). Moreover, “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)

(emphasis in original). In this case, there is no basis beyond speculation and hindsight to suggest that the apparatus disclosed by Furnish even may be used, much less necessarily must be used, in the manner defined in Claims 17 and 19. However, “[The Office] may not... resort to speculation, unfounded assumptions, or hindsight reconstruction to support deficiencies in its factual basis.” *In re GPAC, Inc.*, 57 F.3d 1573, 35 USPQ2d 1116, 1123 (Fed. Cir. 1995). Claim 18 is separately patentable, but is submitted as patentable for at least the same reasons as Claim 17, from which it depends.

Therefore, Applicant respectfully submits that Claims 17-19 are patentably distinguished over Furnish, and kindly requests that the rejection be reconsidered and withdrawn.

With respect to Claim 4, this claim recites, *inter alia*, a slot being aligned with a central axis, the foot having a shape that is asymmetrical relative to the central axis. Gilhuly discloses, at Fig. 6b, a tissue stabilizer having a spiral vacuum channel 51. However, as the figure clearly illustrates, the slot formed by the vacuum channel is not aligned with a central axis of the foot, as recited in Claim 4. Therefore, Applicant respectfully submits that Claim 4 is patentably distinguished over Gilhuly. Claim 5 is separately patentable, but is submitted as patentable for at least the same reasons as Claim 4, from which it depends. Favorable reconsideration and withdrawal of the rejection of Claims 4 and 5 is kindly requested.

With respect to Claims 2, 15 and 51, these claims are separately patentable, but are submitted as patentable for at least the same reasons as the base claims from which they depend. Moreover, the burden is not upon the Applicant to show that any particular feature is critical as a condition to patentability, particularly where there is no prior art to teach or suggest the feature generally, if not specifically. However, there is support in the specification why these features are distinctive.

Regarding Claims 2 and 51, merely any relationship between the two arms would satisfy the function of the claimed 30% or greater increased length of one arm over the other. This feature is distinctive, because if one arm were only marginally longer than the other, the foot as a whole would be less effective to retract other parts of the heart as taught in the specification (see p. 20, lines 3-9). With respect to Claim 15, the lateral tapering surfaces are disclosed in the specification as operative to improve access and/or visualization of the anastomosis site while limiting pressure applied by the stabilizer (See p. 20, lines 10-19). Merely any angle would not satisfy the function of this claimed angle because at excessive angles, 90-degrees in the extreme, visualization would not be improved and access would in fact be hindered. Therefore, these features are further patentably distinguished over their base claims and over Furnish. Favorable reconsideration and withdrawal of the rejection of Claims 2, 15, and 51 is kindly requested.

In light of the foregoing, Applicant respectfully submits that all claims recite patentable subject matter, and kindly requests an early indication of allowability. If the Examiner has any reservation in allowing the claims, and believes that a telephone interview would advance prosecution, he is kindly requested to telephone the undersigned at his earliest convenience.

Respectfully Submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please cancel Claims 9 and 11 without prejudice or disclaimer.

Please amend Claims 1, 5, and 13 to read:

1. (Amended) Apparatus for stabilizing an epicardial surface of the heart, comprising:

a shaft; and

a foot coupled to the shaft, the foot having a first arm, a second arm, and a space between the first and second arms, the first and second arms each having a contact surface for engaging the heart, a proximal end, a distal end and a length defined between the proximal and distal ends and within a plane defined by the bottom surface of said foot, the length of the first arm being longer than the length of the second arm.

5. (Amended) The apparatus of claim 4, wherein:

[the first foot has first and second arms,] the first and second arms [having] each have different shapes.

13. (Twice Amended) An apparatus for stabilizing an epicardial surface of the heart comprising:

an arm;

a foot including a bottom surface having a contact surface for engaging the heart, a slot in which a vessel on the heart may be positioned, wherein at least a portion of the bottom surface is convex; and

the [foot] contact surface is generally convex when viewed along a central axis defined by the slot.